K041434

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ANALOGIC®

510(k) Summary
for
Analogic Corporation
C3 ICG and LIFEGARD™ ICG Hemodynamic Monitors

Date this Summary was Prepared:

May 26, 2004

Submitter's Name and Address:

Submitter's Name:	Analogic Corporation
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Registration Number:	1219601

Contact Person:

Name:	Donald J Sherratt
Title:	Regulatory Affairs Manager
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Device Name:

Proprietary or Trade Name:	C3 ICG
Proprietary or Trade Name:	LIFEGARD™ ICG
Common Name:	Impedance Plethysmograph
Classification Name:	Plethysmograph, Impedance
Classification Panel:	Cardiology
Product Code:	DSB
Code of Federal Regulation:	870.2770

Predicate Device:

The legally marketed devices to which equivalence is being claimed are:

The C3 Patient Monitor cleared under K0309031, and the Cardiodynamics BioZ System cleared under Premarket Notification K974725. The Impedance Cardiography (ICG) parameter incorporated in the C3 ICG and LIFEGARD™ ICG is substantially equivalent to the Cardiodynamics BioZ System.

Description of C3 ICG

The C3 ICG is a compact, lightweight device for measuring, processing, printing, and displaying information derived from six physiological measurements:

- Electrocardiogram (ECG). A three lead ECG is acquired and a waveform can be displayed real-time on the LCD screen or permanently recorded on the optical strip chart recorder. The design of the ECG function is derived directly from the predicate device, the C3 Patient Monitor.
- Pulse Oximetry (SpO_2). Functional Oxygen Saturation is calculated from the ratio of light transmission through the capillary bed at two wavelengths. The SpO_2 subsystem uses software and firmware that is identical to that used in the predicate device, C3 Patient Monitor.
- The temperature is measured using thermistor probes for continuous temperature measurements. Same as in the predicate device, C3 Patient Monitor.
- Blood pressure is measured non-invasively (NIBP) by the oscillometric method. Same as in the predicate device, C3 Patient Monitor.
- End-tidal CO_2 ($EtCO_2$) This method pulls a constant sample flow of exhaled breath from the patient, and analyzes it with a remote CO_2 sensor built into the measurement system. Same as in the predicate device, C3 Patient Monitor.
- Impedance Cardiograph (ICG). This mode uses Thoracic Electrical Bioimpedance (TEB)
- An internal thermal printer records waveforms, hemodynamic parameters and tabular trends on a 50-mm wide strip chart.

The C3 ICG is powered by internal sealed lead-acid batteries or from the mains supply via a battery eliminator. A fully charged battery will power the monitor for two hours.

Description of LIFEGARD™ ICG

The LIFEGARD™ ICG Patient Monitor is a compact, lightweight device for measuring, processing, storing, and displaying information derived from six physiological measurements:

- Electrocardiogram (ECG). A single lead ECG is acquired and a waveform can be displayed real-time on the LCD screen or permanently recorded on the thermal strip chart recorder. The design of the ECG function is derived directly from the C3 Patient Monitor with ICG Parameter.
- Blood pressure is measured non-invasively (NIBP) by the oscillometric method. Same as in the predicate device, C3 Patient Monitor.

- A thermal printer records waveforms, digital vital signs, and tabular trends on a 50-mm wide strip chart.

The LIFEGARD™ ICG monitor is powered by internal sealed lead-acid batteries. A fully charged battery will power the monitor for two hours.

Intended Use:

The purpose and function of the ICG mode of the C3 ICG is to monitor Cardiac Output through the use of Impedance Cardiography (ICG) in adult Males and Females.

When not being used for ICG, the C3 ICG can monitor and display continuous ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (SpO_2), respiration rate, temperature and carbon dioxide (CO_2) on adult and pediatric patients in hospital areas and hospital-type facilities, such as clinics.

The purpose of the LIFEGARD™ ICG is to non invasively monitor Cardiac Output using Impedance Cardiography (ICG) on adult Males and Females and provide continuous ECG, heart rate, non-invasive blood pressure (NIBP), on adult and pediatric patients in hospital areas and hospital-type facilities, such as clinics.

Comparison of Technological Characteristics:

The design of the C3 ICG Monitor is a product update to the design of the C3 Patient Monitor (K030931). The technological characteristics of the C3 ICG are essentially the same as the predicate device - Cardiodynamics BioZ (K974725). Similarly, the characteristics of the LIFEGARD™ ICG are essentially the same as the predicate device - Cardiodynamics BioZ (K974725).

Non-clinical Tests Used In Determination Of Substantial Equivalence:

The predicate device - Cardiodynamics BioZ claims compliance with IEC 601-1 and UL 2601-1 that are previous versions of IEC 60601-1 and UL 60601-1 respectively. The predicate's manufacturer has made no claims of compliance with IEC 60601-1-2 so the electromagnetic compatibility of the predicate is unknown.

The design of both the C3 ICG and the LIFEGARD™ ICG have been thoroughly validated at the unit and system level and meets all elements of their respective Requirements Specifications. This included the following non-clinical tests:

- IEC 60601-1 (including Amendments 1 & 2), an FDA recognized consensus standard for safety of medical electrical equipment.

- Electromagnetic Compatibility Tests in compliance with IEC 60601-1-2:2001. Emissions limits meet Group 1 Class B.
- ECG Performance Testing According to AAMI/ANSI EC-13 (*C3 ICG only when in standard ECG mode. When in ICG Mode, ECG is non-standard single lead*)
- $EtCO_2$ Function Test According to EN 864/1996 *(C3 ICG with CO_2 only)*
- SpO_2 Tested According to EN865, Pulse Oximeters - Particular requirements: 1997 (*C3 ICG only).*
- NIBP Functional Testing to AAMI/ANSI SP10, Electronic or Automated Sphygmomanometers, 2nd Ed.: 1992 and IEC 60601-2-30
- Both new devices were tested to IEC 60601-2-49.
- Mechanical Shock and Vibration Tests were performed in accordance with the IEC 60068 series of standards to ensure transport does not damage the devices.
- Shipping Container Transportation Tests were performed in accordance with IEC 60068-2-27 to ensure that the packaging of the equipment is not adversely affected during shipping.
- Battery Cycle Testing was performed.
- Altitude Tests were performed to ensure that operation at higher altitudes does not adversely affect electrical safety or performance.
- Tests were performed to verify enclosure material robustness and resistance to cleaning materials commonly used in hospitals.

Both the C3 ICG and LIFEGARD™ ICG passed the applicable tests.

Conclusions from Non-clinical Testing

The testing of the C3 ICG and LIFEGARD™ ICG monitors demonstrates that the non-clinical performance is substantially equivalent to the predicate devices - Cardiodynamics BioZ (K974725) and C3 Patient Monitor (K030931).

Other Bench Testing has shown that the hemodynamic monitoring performance of the C3 ICG and LIFEGARD™ ICG are substantially equivalent to the Cardiodynamics BioZ monitor.

Clinical Testing

Clinical testing was performed at the University of Mississippi Medical center where an IRB - approved protocol was performed. 84 patients were sampled, 75 were readable and met Analogic's protocol (6 unreadable and 3 with abnormal EVI). Since the patients with abnormal EVI were readable, their results are included in any analysis for completeness. The study was to compare the predicate device - Cardiodynamics BioZ (K974725) with the Analogic C3 ICG. The ICG circuitry of the LIFEGARD™ ICG is essentially identical to that of the C3 ICG and bench tests have been carried out to verify that they are essentially identical when used for ICG. This meant that only one model of device was needed for the clinical study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2004

Analogic Corporation
c/o Mr. Donald J. Sherratt
Regulatory Affairs Manager
8 Centennial Drive
Peabody, MA 01960

Re: K041434
Trade Name: C3 ICG and LIFEGUARD Impedance Cardiography (ICG) Monitors
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: II (two)
Product Code: DSB
Dated: May 26, 2004
Received: May 28, 2004

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Form (1)

510(k) Number (if known): K041434

Device Name: C3 ICG

Indications For Use:

The C3 ICG Monitor is intended to non-invasively monitor a patient's hemodynamic parameters when in the ICG mode. The hemodynamic parameters include:

Acceleration Index (ACI)
Cardiac Index (CI)
Cardiac Output (CO)
Ejection Time Ratio (ETR)
Ejection Velocity Index (EVI)
Heart Rate (HR)
Heather Index (HI)
Left Cardiac Work Index (LCWI)
Left-ventricular Ejection Time (LVET)
Pre-ejection Period (PEP)
Stroke Index (SI)
Stroke Volume (SV)
Systemic Vascular Resistance (SVR)
Systemic Vascular Resistance Index (SVRI)
Systolic Time Ratio (STR)
Thoracic Fluid Content (TFC)
Thoracic Fluid Volume Index (TFI)
Velocity Index (VI)

The Impedance Cardiography (ICG) function of the C3 ICG is intended for use under the direct supervision of a licensed healthcare practitioner or personnel trained in its proper use within a hospital or facility providing healthcare. The C3 ICG is intended for use on Adult patients that meet the limits specified below:

- Height: 4 ft - 7 ft-6 in (122 - 229 cm)
- Weight: 67 - 350 lb (30 - 159 kg)

When *not* in the ICG mode, the C3 ICG is intended to provide continuous ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (SpO_2), respiration rate, temperature and carbon dioxide (CO_2) on Adult and Pediatric patients within a hospital or facility providing patient care. These are indications previously cleared under K030931.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041434

Indications For Use Form (2)

510(k) Number (if known): K041434

Device Name: LIFEGARD™ ICG

Indications For Use:

The LIFEGARD™ ICG Monitor is intended to non-invasively monitor a patient's hemodynamic parameters. The hemodynamic parameters include:

Acceleration Index (ACI)
Blood Pressure (built-in NIBP)
Cardiac Index (CI)
Cardiac Output (CO)
Heart Rate (HR)
Left Cardiac Work Index (LCWI)
Left-ventricular Ejection Time (LVET)
Pre-ejection Period (PEP)
Stroke Index (SI)
Stroke Volume (SV)
Systemic Vascular Resistance (SVR)
Systemic Vascular Resistance Index (SVRI)
Systolic Time Ratio (STR)
Thoracic Fluid Content (TFC)
Velocity Index (VI)

The LIFEGARD™ ICG is intended for use under the direct supervision of a licensed healthcare practitioner or personnel trained in its proper use within a hospital or facility providing healthcare. The LIFEGARD™ ICG is intended for use on Adult patients that meet the limits specified below:

- Height: 4 ft - 7 ft-6 in (122 - 229 cm)
- Weight: 67 - 350 lb (30 - 159 kg)

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041434